Technegas Generator User Manual

10069 European English Version

NOTICES

Attention

The information found in this manual is the latest information at the time of delivery. However, Cyclomedica reserves the right to change specifications and recommended procedures without prior notice.

Should this occur and affect the use of your Technegas Generator, you will be advised of any upgrades or recommended procedural changes which will be accompanied by amendment sheets for this manual.

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Cyclomedica Australia Pty Ltd.
Building No. 75,
Business & Technology Park,
New Illawarra Road,
LUCAS HEIGHTS. NSW. 2234
AUSTRALIA

Phone: +61 2 9541-0411.
Facsimile: +61 2 9543-0960.

email: *enquiries@cyclomedica.com.au*

TABLE OF CONTENTS

Section	Title	Page No.
1	**INTRODUCTION**	5
	What is Technegas?	5
2	**USER RESPONSIBILITY**	6
	Traceability	6
	Cautions	6
3	**SAFETY IN USE**	7
	Safe Handling of Compressed Gas Cylinders	7
	Use of Gloves	7
	Warnings	7
	Safe Patient Delivery of Technegas	8
4	**OPERATING THE TECHNEGAS GENERATOR**	9
	Installation Requirements	9
	Power Supply	9
	Argon Supply	9
	Additional Items Required	9
	Other Requirements	9
	Connecting the Argon Gas	9
	Operating the Gas Bottle Regulator	10
	Fitting the Purge Filter and Lid	10
	Battery Charging	11
	Operating the CANCEL Button	11
	Operating the Technegas Generator	11
	Preparing and Fitting the Pulmotec™ Crucible	12
	Gas Flow Monitor	14
	Case Temperature Too High	14
5	**ADMINISTRATION OF TECHNEGAS**	16
	Introduction	16
	Recommended Dose	16
	Administration to the Patient	16
	General Comment	18
6	**DISPOSAL OF CONTAMINATED ITEMS**	19
	List of Contaminated Items	19
	Disposal of Radioactively Contaminated Items	19
7	**LCD MESSAGES AND DESCRIPTIONS**	20
	Operational Messages	20
	Service Messages	25
8	**TECHNEGAS LABEL DESCRIPTIONS**	26

TABLE OF CONTENTS

Section	Title	Page No.
9	**USER MAINTENANCE AND SERVICE**	30
	User Maintenance	30
	Cleaning the Generator	30
	Changing Contact Assemblies	30
	Changing the Purge Filter	31
	Service	31
	Preventive Maintenance Service	31
	General Service of Fault Conditions	31
10	**SPECIFICATIONS**	32
	Protection Against Electric Shock	32
	Electromagnetic Compatibility	32
	Environmental	32
	Consumables	32
	General	33
11	**DOSIMETRY**	34
	Radiation Dosimetry	34
12	**TECHNEGAS GENERATOR SPARES**	35
13	**REFERENCES**	36

What is Technegas?

Technegas is an ultra-fine suspension of carbon micro-particles labelled with technetium(Tc-99m).

Technegas preparation takes place in a specially designed machine, called the Technegas Generator, where a solution of sodium pertechnetate(Tc-99m) is loaded into the Pulmotec™ crucible and evaporated until dry. Technegas is then generated by heating to 2550 °C in an atmosphere of pure argon.

The Technegas particles have been determined as being hexagonal platelets of metallic technetium(Tc-99m) closely encapsulated with a thin layer of graphitic carbon, the size distribution of Technegas particles being around 30-60 nm with 80% of the particles being below 100 nm. The ratio of the platelet thickness to diameter is around 1 : 10 in most cases.

Technegas is intended to be administered to the patient within 10 minutes of its generation. After 10 minutes, to prevent accidental use of expired diagnostic agent, the Technegas Generator inhibits the delivery to the patient and the chamber is automatically purged to a filter system to trap excess Technegas. Note that prolonged storage of Technegas promotes aggregation into larger particles and the migration of those particles to the walls of the chamber.

User Responsibility

- *The User of the Technegas Generator is responsible for providing an appropriate operational environment as defined by the specifications contained in this manual. Incorrect equipment operation may occur if the operational environment is unsuitable. The Technegas Generator will meet the specifications described in this manual and in the package inserts and labels affixed to its consumables when it is installed and operated in accordance with those labels and instructions.*

- Keep the Generator in good order. User Maintenance should be carried out by the User at the recommended periods defined in the manual to ensure reliable Generator operation. The User should also ensure that the manufacturer recommended 6 monthly services are strictly observed and carried out by your local distributor.

- A defective product should not be used. Any defects must be promptly recorded. Parts that are worn, defective or suspected of same should be replaced immediately. Cyclomedica recommends in the above instance that the User contact their local distributor for service advice.

- The Technegas Generator and its accessories bear regulatory marks to show compliance to Medical Device standards. No part of this product should be repaired or modified in any way other than in accordance with those standards.

- The user of the Technegas Generator and its accessories shall take sole responsibility for any malfunction which results from the improper use, faulty maintenance, improper repair, damage, alteration or modification by anyone other than an authorised Cyclomedica representative.

Traceability

From time to time additions to the product file held by the user, including but not limited to service notes, changes in literature, device notifications etc., may become necessary. A condition of sale is therefore traceability of the product at all times. Please register ownership with your local distributor at the time of installation by completing the Warranty Card. Should there be any change of ownership of the Generator then your local distributor should be notified in writing immediately.

Cautions

- Before use, always wet the *Pulmotec*™ crucible using ethanol adding the pertechnetate(Tc-99m*)* immediately after. Do not use methylated alcohol as it may leave residues on evaporation that could lead to pyrolysis products in the gas generation stage.
  Also, care must be taken when handling Pulmotec™ Crucibles to avoid the introduction of foreign substances from any source. Always use clean gloves and inspect the crucible at the time of installation into the Technegas Generator

- Ensure that the *Pulmotec*™ crucible is not overfilled. The meniscus should be concave or flat not convex.
- Always turn off the Argon gas when the supply is disconnected from the Technegas Generator to avoid waste. For safety, use the order of operations recommended by the Regulator supplier or manufacturer.

- Dispose of the used consumables as contaminated waste, both radioactive and biologically hazardous.

Safe Handling of Compressed Gas Cylinders

Cylinders of compressed gas are very heavy, and unstable if left standing without some restraining mechanism.

Cyclomedica recommends that the Argon gas supply be piped in from an external location as is the usual practice with hospital reticulated gases. Given the lifetime of the technology, the investment in this safety precaution is minor. In any case, no gas cylinder should be stored without a restraint, usually a bracket and chain, to prevent falling.

The responsibility of Cyclomedica, is limited to the Technegas machine up to the low pressure regulator, and where supplied by Cyclomedica, the high pressure regulator. The company can in no way be held liable for negligence in the restraining or handling of high pressure gas cylinders.

Use of Gloves

During the various steps of generation and use of Technegas the following considerations are paramount in maintaining a clean working environment and in minimising the risk of contamination:

Whenever the internal parts of the generator are handled or open during loading of new crucibles and radioactivity, or during contact replacement or any other procedure gloves must be worn (unless the unit has not been used for at least three days).

Gloves must be removed and disposed of using standard techniques immediately prior to touching anything else such as the drawer close interlock knob and the CLOSE button.

Warnings

- **USE ONLY Solution of Sodium Pertechnetate(Tc-99m) of European Pharmacopoeia grade or equivalent in the Technegas Generator**

- In the interests of reliable operation and basic hygiene, do not attempt to use a Patient Administration Set (PAS) on more than one patient.

- Do not clean a PAS and attempt to use it again. Both gas and liquid sterilising damage the valve mechanism and the wool-based filter, causing unreliable operation and potential bacterial contamination of the machine. **Disposal of the PAS is mandatory after a single use.**

- **Do not allow repairs to be carried out on the Technegas Generator by unauthorised personnel.**

- Do not insert cleaning brushes or other foreign objects through the various valves, openings or holes in the device or its consumables. Damage may result which will make the unit unserviceable.

- Do not use the unit for any other purpose than that specifically indicated in the product literature.

- Do not autoclave the unit or its consumables as this will damage the circuitry and other components.

Safe Patient Delivery of Technegas

To avoid the escape of Technegas into the room the following steps should be observed;

- Never open the patient delivery valve until the generator is coupled to the patient using the PAS or a Cyclomedica approved alternative mouthpiece.

- Always ensure that the patient continues to breathe through the PAS whilst connected to the Technegas unit with the delivery knob released for at least five breaths after the cessation of Technegas inhalation. This manoeuvre clears Technegas from the delivery tubing and the patient's conducting airways.

- If you suspect that the patient will not comply with the mouthpiece of the administration set choose a more suitable delivery system from the range of alternatives available. Note that this may be done in the course of the inhalation procedure.

Moving the Technegas Generator Safely

To avoid problems associated with moving the Technegas Generator please observe the following warnings:

- When moving the Technegas Generator, disengage the wheel locks and always push or pull the unit by using the handles provided moving the Technegas Generator at a rate of no more than a slow walking pace. Do not attempt to move the Technegas Generator with the wheel locks engaged or in a manner that you cannot safely control. eg: swinging the generator around or moving it at a speed faster than a slow walking pace.

- Do not wheel the Technegas Generator Trolley over obstacles on the floor or over uneven surfaces that may block or seize the wheels eg: gaps between an elevator and the floor, gamma camera rails and cables.

- Do not load the trolley with heavy items such as Gas Bottles for transport. Always move Gas Bottles and other heavy equipment using specialised transport equipment that is appropriate for carrying such items.

Installation Requirements

Power Supply

The User must provide a mains power line dedicated for use with the Technegas Generator - 200 to 230/240V, 50/60Hz 20A.

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Argon Supply

High Purity or Laboratory Grade Argon ≥99.99% pure.

CAUTION

Some gas mixtures are sold for use in argon arc welding such as “Argoshield" or welding grade Argon, etc. They usually contain small quantities of oxygen and other gases. **These mixtures must not be used** as they are not appropriate for human use.

Technetium Generator Eluate - *Recommended **Pulmotec**™ crucible loading is between 400 and 900 MBq (10-25 mCi) of Sodium Pertechnetate(Tc-99m) in an average **Pulmotec**™ crucible volume of 0.14mL (normal saline). Thus a radioactive concentration of 4000 to 9000 MBq/mL (100 to 250 mCi/mL) is required.* If such a high radioactive concentration eluate is not available it is possible to carry out multiple *Pulmotec*™ crucible loadings by interrupting the automatic generation cycle after the evaporation phase (Simmer), this is done by pressing the CANCEL button **TWICE** in two seconds, opening the drawer, re-filling and re-evaporating. Please note that the crucible does not require to be re-wet with ethanol prior to re-filling.

Additional items required

- a 1 mL Syringe for loading with Sodium Pertechnetate(Tc-99m).
- Syringe shield.
- Disposable gloves.
- Pure ethanol, greater than 95%.
- Watch glass or petrie dish.
- 1 mL needleless syringe for wetting with ethanol.
- Forceps (supplied with Technegas Generator.)

Other Requirements

- Assign an area within the Nuclear Medicine department, preferably near the imaging room, for production of Technegas and storage of the unit.

- Allow space for the safe storage of used *Pulmotec*™ crucibles and PAS for a minimum of five days before final disposal as non-radioactive waste or as per the regulations and/or licences of the local Competent Authorities.

- Be sure there is a general purpose electrical power outlet (10 Ampere or more) which is rated to deliver 20 Ampere for 15 seconds. Some circuit breakers (10 Ampere) will open during the burn cycle, however, the incidence is rare and may be remedied by fitting a Slow-blow standard circuit breaker or designated power outlet.

Connecting the Argon Gas

Before commencing the production cycle, the Argon gas should be connected and turned on. To do this, plug in the gas outlet hose to the gas inlet of the Technegas Generator, and ensure the self-latching mechanism has engaged. Where a high pressure gas bottle is used, ensure that the bottle is securely fixed to a wall or as per your local requirements for safety.

REAR PANEL **GAS INLET**

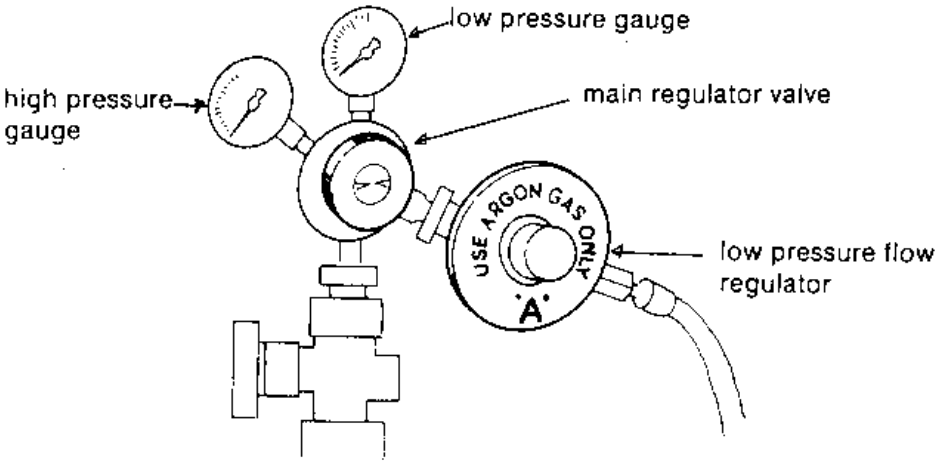
Operating the Gas Bottle Regulator

Ensure that the regulator mechanism is firmly bolted to the gas supply. Ensure that the regulator is fully off then turn on the gas at the bottle. Rotate the main regulator valve until the low pressure gauge registers 12 litres per minute or as indicated by the “green” area of some regulators.

The following order of operations for turning on and off the Argon gas regulator is recommended to avoid damage to the regulator itself.

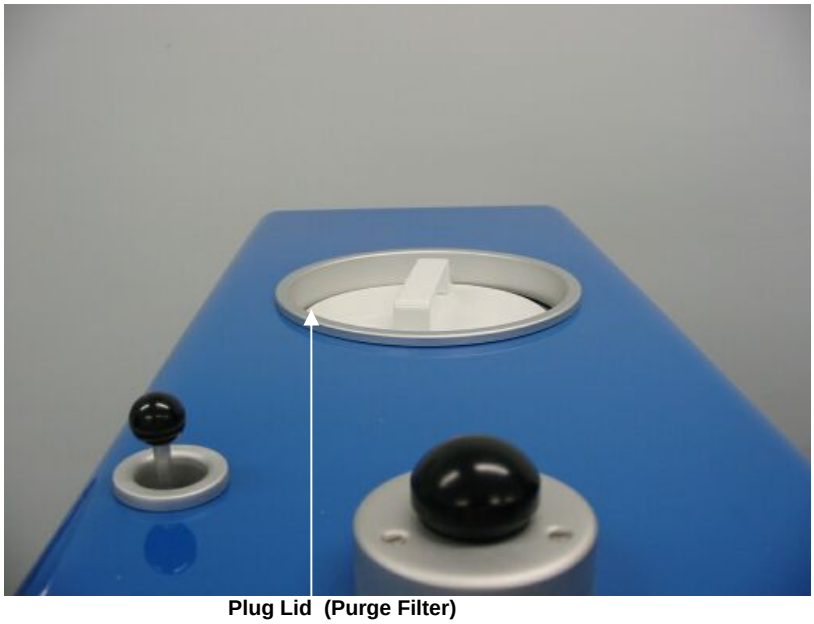
TO TURN ON: Bottle On **first**, then Regulator On.

TO TURN OFF: Regulator Off **first**, then Bottle Off.



Fitting the Purge Filter and Plug Lid

Check that the purge filter and plug lid are correctly installed in the top of the generator.



Plug Lid (Purge Filter)

Battery Charging

Plug the Technegas unit into the electrical power outlet and switch on using the main switch located at the rear of the generator. You are advised to leave the unit plugged in and turned on when not in use to keep the battery fully charged.

A flat battery will not be evident until you try to deliver Technegas to your patient!

Operating the "CANCEL" Button.

The CANCEL button needs to be pressed **TWICE** within two seconds to activate a "CANCEL" operation. This eliminates the risk of cancelling an operation accidentally.

OPERATING THE TECHNEGAS GENERATOR

- Switch on the Technegas Generator, initially the display will show the name Cyclomedica for 4 seconds. If the purge has not been carried out, then it will then check if the drawer is closed and give a 3 minute purge. This purge is to ensure that no radioactive Technegas from a previous test will escape into the atmosphere when the drawer is opened. If the Purge filter or filter lid is not installed an alarm will sound and the generator will not proceed until the filter and lid are correctly installed. (Refer page 31 for correct installation).

Please Note: At the completion of the patient delivery process and the removal of the PAS from the Generator, Cyclomedica recommends that the operator reconnects the Generator to the mains power, switches it on and allows the 3 minute purge cycle to be carried out. This will keep the machine cleaner and allow a period of battery recharging.

The display will then read:

OPEN DRAWER TO
CHANGE BOAT

- To do this, simply press OPEN. There is no need to hold the button, however, if necessary CANCEL will immediately stop the drawer moving. If there was a crucible in the machine from a previous burn, it will have been broken, so it, or its pieces, should be removed first (this is to ensure that the *Pulmotec*™ crucible is not accidentally re-used).

There is a small stainless steel tray immediately below the crucible which is removable to facilitate this step. The contacts which hold the *Pulmotec*™ crucible can be opened by using the lever under the platform on the left-hand side.

CAUTION The lever and all other internal components of the generator are contaminated during Technegas generation. Be sure disposable gloves are worn at this stage and take care to practice proper anti-contamination procedures by removing and replacing gloves between touching contaminated and non-contaminated components.

Preparing and Fitting the Pulmotec™ Crucible

For the Preparation of Technegas, Users should follow the details in the Package Insert for the *Pulmotec*™ Crucible (Instructions for Use and handling) making reference to the Package Insert for the Patient Administration Set (PAS) and this Manual as required.

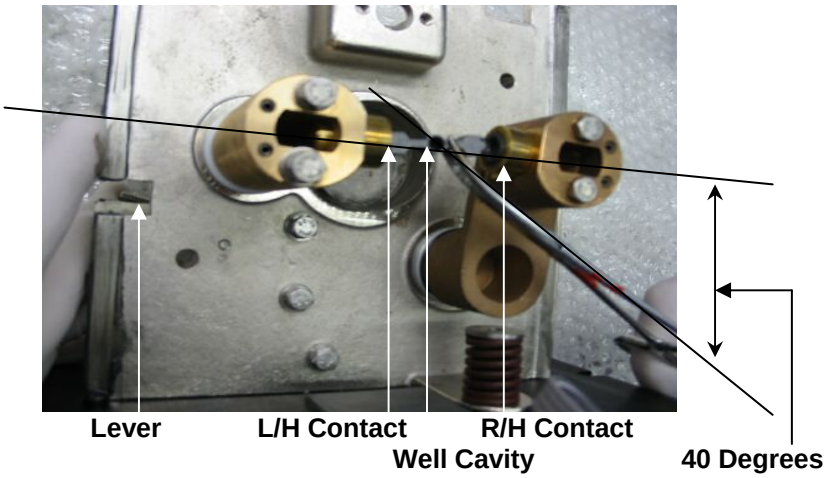
Note: For the purposes of accuracy, the words "electrode" and " *Pulmotec*™ crucible" appear in this manual. On the Technegas Generator display they appear as "CONTACT" and "BOAT" or “CRUCIBLE” respectively.

- Remove the *Pulmotec*™ crucible from its packaging using the forceps supplied with the Generator, and place it on a watch glass for suitable support.

- Wet the well of the *Pulmotec*™ crucible by filling with absolute or 95% ethyl alcohol using a 1 mL needle-less syringe. Draw back any excess ethanol with the same syringe leaving the crucible wet with ethanol.

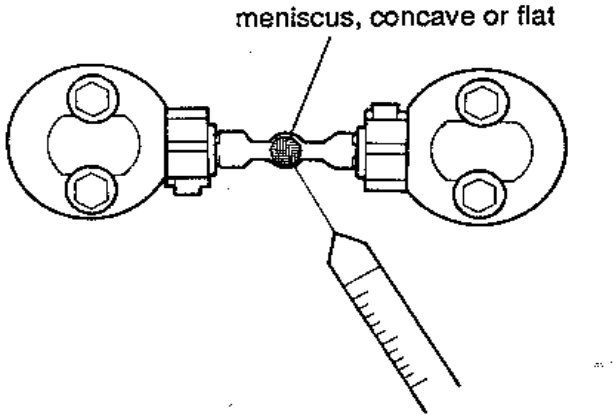
- Pick up the wetted *Pulmotec*™ crucible using the forceps holding them in the right hand with the forceps gripping the top and the bottom of the crucible, not the sides. Top and bottom are determined by having the well of the *Pulmotec*™ crucible in the upright position. The crucible axis should be at an approx. 40° to the right hand side of the forceps.

- With a gloved left hand push the lever under the platform towards the back of the machine, thus opening the contacts. Place one end of the *Pulmotec*™ crucible into the left hand contact and align the other end of the *Pulmotec*™ crucible with the right hand contact. Slowly release the lever so that the right hand contact is made. Unless good contact is made a low Technegas yield may result. Rotate the *Pulmotec*™ crucible gently backwards and forwards on its axis a few times prior to simmering to ensure good contact. Rotate the *Pulmotec*™ crucible to ensure the well cavity is upright.



CAUTION This procedure should be carried out carefully, as the crucible is very brittle.

- Load the *Pulmotec*™ crucible with Eur. Ph. sodium pertechnetate(Tc-99m) generator eluant (note the crucible must be wet from the ethanol before the solution of sodium pertechnetate(Tc-99m) is added), use a 1mL syringe with a suitable needle and ensure that no bubble of liquid rises above the top of the *Pulmotec*™ crucible (maximum volume 110ul)



- To close the drawer press the drawer interlock knob on the top FIRST, then the CLOSE button. Keep both depressed until the drawer is fully closed and the drawer light has gone out.

Draw Interlock Knob

Close Button

If either is released before the drawer has stopped moving it will immediately re-open. This two handed operation is a safety precaution.

Do not attempt to put anything in the drawer opening, nor to interfere with the process as you may damage the seal of the generator. Do not operate the mechanism if you suspect anything may obstruct normal operation.

CAUTION - WHENEVER THE GENERATOR IS NOT IN USE, THE DRAWER MUST BE CLOSED TO AVOID ACCIDENTAL CONTAMINATION OF PERSONNEL.

The display will then read:

PRESS START TO
INITIATE SIMMER

- When START is pressed the chamber will be checked for correct sealing by a leak test, then the simmering, purging starts. This cycle is 6 minutes in length, indicated by a count-down time that is displayed during this stage. Only the CANCEL button is active during this time. If it is necessary to "double dose" the *Pulmotec*™ crucible, ie. not enough activity could be added in one loading, then press the CANCEL button **TWICE** within two seconds at the end of the simmering, purging stage. This will restart the program, allowing the drawer to be opened again. There is no need to re-wet the crucible with alcohol.

Gas Flow Monitor

Gas flow into the unit is continuously monitored . If the gas flow is too high or low because of an emptying bottle or a valve not fully on, the process will halt and the unit will "beep" while displaying the message to "gas flow too high/low". As soon as the fault is corrected, the machine resumes the process.

Case Temperature Too High

The Technegas Generator has a Duty Cycle of 2 Gas Generations per hour. Where used more frequently, the Generator Chamber may become too hot for effective use. In this case a message is displayed to indicate to the user that they must wait for the Generator to cool before continuing.

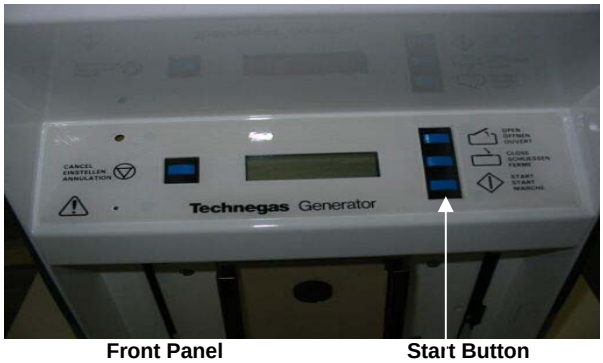
A limit of 48 degrees Celsius has been introduced to the case temperature, above which the unit will not operate. This should not pose any problem if the machine is run no more frequently than twice an hour - the duty cycle specified as maximum in this manual.

The unit is now ready for the final stage of Technegas generation. Before proceeding further, position the patient ready for inhalation and open a fresh PAS beside them as reassurance. The patient must be familiar and comfortable with breathing through the mouthpiece while their nose is blocked with the clamp supplied. If the patient defeats the mouthpiece on exhalation then a percentage of the inhaled Technegas can be released into the room. This can cause a rise in camera background radiation.

The six minute simmer and purge routine creates a convenient time to rehearse the patient in the procedure and minimise the risk of failure.

If the generator is left longer than 15 minutes while preparing the patient then the generator will recheck the presence of argon gas. This is repeated every 15 minute thereafter. Note that the burn stage cannot be commenced until after the check is completed and the prompt appears to START the burn.

- Press the START button now and the burn will commence, raising the *Pulmotec*™ crucible temperature above 2550°C for 15 seconds. Your Technegas is now prepared and ready for inhalation by the patient. Refer to the Section of this Manual on Administration of Technegas.



Front Panel **Start Button**

The display will then read

VERIFYING BURN

- this message holds for 3 seconds and then changes to:

DISCONNECT THE MAINS PLEASE

- Also disconnect the Argon gas (be sure to turn the Argon supply off at the regulator as recommended before disconnecting the Argon, otherwise wastage will occur) then wheel the machine to the camera room. **The Technegas is available to be administered for 10 minutes after generation.** This is indicated by a countdown time on the display. While the mains power has been disconnected the unit remains powered by an internal battery.

Introduction

Once generated, Technegas must be administered to the patient as soon as possible and certainly within 10 minutes of generation. The patient should be prepared for administration during Technegas generation. Ideally, the patient should be positioned so that the activity entering the lungs can be monitored with a gamma camera.

Recommended Dose

Refer to the Pulmotec™ crucible package insert for details on the dose to administer to the patient"

The dose to the patient must be set by the User's Nuclear Medicine Department, please consult your Department Director and/or Radiation Safety Officer.

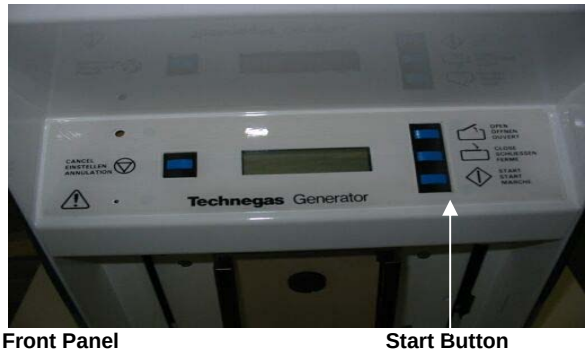
Administration to the Patient

For the Administration of Technegas to a patient, Users should follow the details in the Package Insert for the Patient Administration Set (PAS) making reference to the Package Insert for the *Pulmotec*™ Crucible and this Manual as required.

- Select the desired mouthpiece and allow the patient to familiarise themselves with it during the preparation time of Technegas as described in the **PAS Package Insert**. When ready, fit a nose clip to the patient to prevent the patient breathing through the nose.

Patient posture affects the distribution profile of Technegas in the lungs in response to the gravitational effect on blood distribution. Every effort should be made to ventilate the patient in the same posture as they will adopt for the MAA injection. Experience has shown that wherever possible, patients should be supine and the gamma camera positioned for a posterior view. Body movement and breathing irregularities are greatly reduced if your patient is in a comfortable, but restrained supine position.

- Press the **START** button to produce Technegas.



Front Panel **Start Button**

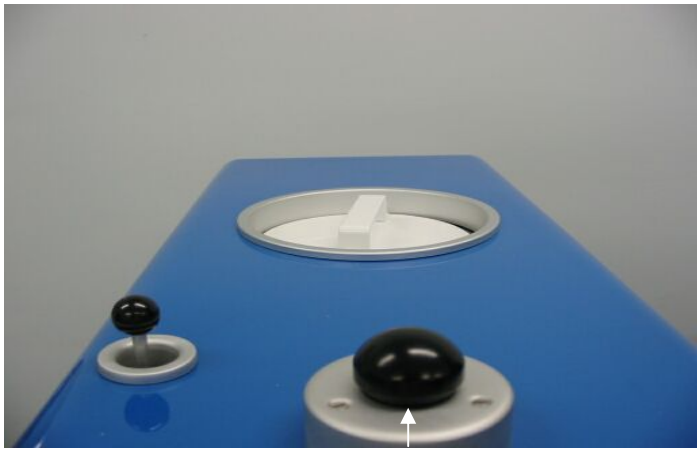
- Disconnect the unit from the gas and mains power and wheel it to the patient.

- Connect the open end of the tubing of the PAS to the generator by pushing it over the Technegas release port and locking the bayonet fitting with a small clockwise twist. Encourage the patient to breathe normally through the mouthpiece. Assure the patient at this time that they are breathing room air.

- Press the **START** button to release the patient delivery valve.

Start Button

- When the patient is comfortable and confident breathing through the mouthpiece, request the patient to exhale then press down the patient delivery knob firmly as the patient begins to inhale.



Patient Delivery Knob

- Ask the patient to breathe in the Technegas described in the Mode of Administration section of the *Pulmotec*™ **Crucible Package Insert** using the breathing method best suited to the patient.

IMPORTANT: The administration techniques are described in the Package Insert for the *Pulmotec*™ Crucible. The chosen technique will depend on the health condition of the patient.
Method 1: Deep and slow breathing from the residual functional capacity (calm and expiration) followed by a 5 second pause of inspiration.
Method 2: Deep breathing with deep inspirations without pause
Method 3: Rapid and deep inspirations from the residual functional capacity followed by a pause of about 5 seconds in inspiration.

HINT: Encouraging the patient to imitate sucking drink through a straw seems to improve the efficiency of the inhalation.

- Watch the count rate and repeat this operation until the required activity is present in the lungs.

- Release the delivery valve after the required activity is present, and allow the patient to breathe air again through the mouthpiece tube assembly. It is important for the patient to breathe through this assembly for five to six breathing cycles after Technegas has been administered to clear Technegas from the tubing and the patient airways.

NOTE: 1 The delivery knob may be pressed and released continually during the inhalation process to regulate intake of Technegas. It bypasses to room air when not depressed.

NOTE: 2 Some patients may endeavour to breathe in and out around the mouthpiece, thus defeating the effectiveness of the test and rapidly contaminating the room air. The risk of this can be reduced by carefully explaining the importance of the test to the patient, allowing the patient a practice run with the mouthpiece. (page 16) and if necessary manually holding the lips closed with gloved hands. For elderly patients a pleasant tasting gel is available to form a good seal around deeply fissured lips.

- After the patient has received the required amount of Technegas the patient valve should be released and the CANCEL button pressed **TWICE** in two seconds. The unit will then shut down.

Cancel Button

- Return the unit to the preparation area, reconnect Argon and electrical power, switch on and allow the system to purge residual Technegas immediately. This will reduce the level of Carbon build up in the chamber in between service calls.

NOTE: It is important to leave electrical power on to the unit to maintain battery charging.

General Comment

If the radioactive signal from your patient is too low, the most probable cause is that the patient has defeated the mouthpiece and breathed room air.

List of Contaminated Items

- The *Pulmotec*™ crucible
- The USED Patient Administration Set (PAS)
- Purge filter
- Crucible contacts
- Gloves

NOTE: The *Pulmotec*™ crucible and the Patient Administration Set are **single use items** and should be handled as follows:

Use disposable gloves during handling

The *Pulmotec*™ crucible is broken automatically following Technegas generation to prevent accidental re-use which would result in erratic yields. The debris is collected in a tray beneath the contacts, and will contain a residue of radioactivity. It should be treated as low level radioactive waste.

The PAS and mouthpieces should be treated similarly with additional consideration given to the interests of basic hygiene.

The Purge filter and crucible contacts should be changed as specified on pages 30 & 31 and decay stored or disposed of as low level radioactive waste.

Any component removed or replaced from the internal systems must be handled as if it too were contaminated; although, the degree of contamination will depend on the length of time that the unit has stood since last used.

Disposal of Radioactively Contaminated Items

The disposal of radioactive and infectious waste are subject to the regulations and/or the appropriate licences of the local Competent Authority.

Where advice on disposal is required, Cyclomedica recommends that users contact these administrations.

1. "START" RELEASES GAS VALVE

Press the START button to unlock the patient delivery valve when the Technegas Generator is fitted with a manual valve.

2. * NO BOAT ***OR BAD CONTACTS**

When the simmer starts the power required to reach simmer temperature is monitored and if found to be in error the machine halts and displays this message. Normally it will mean there is no crucible. If the *Pulmotec*™ crucible is present, rotate the crucible back and forth a few times and try again. Next, try a new *Pulmotec*™ crucible followed by replacing the fixed contacts. If still in error call Service.

3. ***WARNING*CHECK FILTER**

This message is displayed if the Purge filter or filter lid is missing when the machine requires the use of Argon gas. This would normally occur immediately after switch on. Check the positioning of the Purge Filter and lid.

4. AMBIENT PRESSURE OUT OF RANGE

This means that the external ambient pressure is beyond the range of the limits of the generator. Try switching off, then on again. If still in error, call Service.

5. BAD OUTLET VALVE

This message is displayed when a fault has been detected in the gas outlet valve. Try switching off, then on again. If still in error, call Service.

6. BOAT EXCEEDED ALLOWABLE TEMP

This message is displayed when the temperature of the *Pulmotec*™ crucible has exceeded the upper limits during the full burn stage. Try repeating the entire Generation procedure again by switching off, then on again. If still in error, call Service.

7. BOAT FAILED TO REACH FULL TEMP
LOW YIELD PRESS START TO CONTINUE

You have the option here to press START to deliver Technegas produced or to repeat the complete generation procedure. This message is a warning to carry out user maintenance by checking/tightening the contacts. If this message continues after checking/replacing the contacts, call Service for further advice.

8. BURN VERIFIED

No action required. The generator is checking that a burn has been carried out.

9. CASE TEMPERATURE TOO HIGH WAIT

The Technegas senses that it's ambient temperature is too high. No more than two burns per hour is specified.

10. CHAMBER FAILED LEAK TEST

This means that there is a slight leak in the chamber and the most probable cause is that something may be jammed in the drawer front panel. Check this then retry. If still in error call Service.

11. CHAMBER OPEN OR NO ARGON GAS
If no pressure is found in the chamber 10 seconds after opening the gas inlet valve this message will be displayed. Normally this means that the Argon gas is either not connected or not turned on. Other possible causes could be low pressure in the Argon cylinder or something jammed in the drawer front panel.

12. CHANGE CONTACTS OR CLOSE DRAWER
The drawer can now be closed until it is a convenient time to change the contacts. If the contacts are to be changed, switch the power off with the drawer open and refer to the User Maintenance and Service Section pages 30 & 31.

13. CHANGE CONTACTS WITHIN 9 BURNS scrolling with:
PRESS START TO CONTINUE
If 41 burns have been completed on the Technegas Generator the above messages will be displayed. This indicates that there are 9 burns left on the current crucible contacts. When the 9 burns have been completed the Technegas Generator will not allow further burns until the crucible contacts have been changed. Pressing START at this stage will return the display to the normal screen message.

14. CHECKING FOR ARGON GAS
No action required. The Generator is checking for connection to a Gas supply

15. CHECKING FOR GAS LEAKS
No action required. The Generator is self-testing for chamber seal.

16. CHECKING INLET & OUTLET VALVES
No action required. Generator self-test.

17. CLOSE = PERTECHNEGAS OPEN = TECHNEGAS
This message appears only when the Technegas Generator is used in conjunction with a Ventilation Assistance Unit (VAU).

18. CONTACTS CHANGED ?? Scrolling with: **OPEN = NO CLOSE = YES**
The above message is displayed when the power is switched back on after changing the contacts. Pressing the appropriate button (OPEN or CLOSE) will allow normal operation.

19. DISCONNECT THE MAINS PLEASE
Disconnect the Mains supply and the Argon Gas.

20. DRAW MIDWAY OPEN OR CLOSE
Try closing the drawer further or opening fully. If this does not work, try switching off, then on again. If still in error, call Service.

21. ERROR IN READING PRESSURE
This message is displayed when there is a fault in the pressure detecting section. Try switching off, then on again. If still in error, call Service.

22. GAS READY TO USE WITHIN 00:00
Indication of time limit (minutes: seconds) within which you must use the Technegas.

23. LOAD BOAT THEN CLOSE DRAWER
Install the moistened *Pulmotec*™ crucible, Load the *Pulmotec*™ crucible with the sodium pertechnetate(Tc-99m) and close the drawer. See Page 12.

24. OPEN = NO CLOSE = YES
The Generator requests the user to select a control option.

25. OPEN DRAWER AND CHANGE CONTACTS scrolling with: **PRESS START TO CONTINUE**
The above message occurs when 50 burns on the current crucible contacts have been completed. At this stage START should be pressed, and the drawer opened.

26. OPEN DRAWER TO CHANGE BOAT
Open the drawer to load a *Pulmotec*™ crucible.

27. PLEASE ENSURE THE OXYGEN IS ON
This message appears only when the Technegas Generator is used in conjunction with a Ventilation Assistance Unit (VAU).

28. WAIT PURGING 3.00
The Generator is purging (cleaning) the chamber prior to allowing the drawer to be opened.

29. PLEASE ENSURE THE OXYGEN IS ON.
This message appears only when the Technegas Generator is used in conjunction with a Ventilation Assistance Unit (VAU).

30. PRESS CANCEL IF FINISHED
Press the CANCEL button when delivery of Technegas to the patient has been completed. See Page 18.

31. PRESS CANCEL TO RESTART
Press the CANCEL button **TWICE** in 2 seconds to cancel an operation and restart the Generator.

32. PRESS DRAWER INTERLOCK KNOB
If the CLOSE button is pressed without first pressing the interlock knob this message will be displayed along with an audible alarm.

33. PRESS START TO CONTINUE
Press START to return to normal generator program.

34. PRESS START TO INITIATE BURN
Press the START button to begin the burn cycle. Be sure you are ready to do so.

35. PRESS START TO INITIATE SIMMER
Press the START button to begin the simmer cycle.

36. SET TO GENERATE PERTECHNEGAS
This message appears only when the Technegas Generator is used in conjunction with a Ventilation Assistance Unit (VAU).

37. SET TO GENERATE TECHNEGAS.
This message appears only when the Technegas Generator is used in conjunction with a Ventilation Assistance Unit (VAU).

38. SIMMER CONTROL OUT OF RANGE
This means that an adjustment to the Simmer Control is necessary. Try switching off, then on again. If still in error, call Service.

39. SORRY THE GAS IS TOO OLD TO USE
This message is displayed when 10 minutes has elapsed after the Technegas generation cycle has been completed. It means that the gas is no longer useable and a repeat of the entire Technegas Generation procedure is necessary if Technegas is still required.

40. SWITCH OFF AND CALL MAINTENANCE
The Generator has detected an error. Call Service for advice.

41. SWITCH OFF AND CHANGE CONTACTS scrolling with: **PRESS START TO CONTINUE**
The Technegas Generator should now be switched off and the crucible contacts changed. If this is inconvenient at this stage, then pressing START will display the message:

42. THE GAS FLOW IS TOO HIGH
The Generator detects a high gas flow. The procedure resumes automatically when gas flow is reduced to the correct level.

43. THE GAS FLOW IS TOO LOW
Check argon gas supply gauges and lines to machine, to ensure correct flow. Replace gas bottle if necessary.

44. TRIAC FAILURE
Try repeating the entire Generation procedure again by switching off, then on again. If still in error, call Service.

45. TURN OFF AND TRY AGAIN
Turn Generator off and try procedure again.

46. WAIT GENERATING GAS
No action required. The Generator is in the process of generating Technegas

47. WAIT PURGING CHAMBER
No action required. The Generator is clearing the chamber of any remaining Technegas.

48. WAIT SIMMERING PURGING
No action required. The Generator is in the Simmer stage.

49. WAIT TEST CANCELLED
This message is displayed if the CANCEL button is pressed during the simmer stage. It is not an error message and requires no action.

50. "START" ENABLES GAS VALVE
Press the START button to unlock the patient delivery valve when the Technegas Generator is fitted with an electronic valve.

51. XXX BURNS, CONTACTS XX MORE

This message indicates the total number of burns and the remaining number of burns for the contacts.

52. LOW YIELD, CHECK CONTACTS

This message indicates that the Technegas Generator detected a possible LOW YIELD and requests the user check that the contacts are tight and in good condition.

53. BATTERY ON CHARGE

This message indicates that the Technegas Generator is in the Battery Charge mode. Switch the Generator off and then on again to restart normal operation.

Where any one of the following Service Messages are displayed, call Service to seek advice. These messages are for functions not available to the User.

1. PURGE TEST OFF
No action required. Service Message.

2. SIMMER TEST ON
No action required. Service Message.

3. TEST PATIENT VALVE OFF
No action required. Service Message.

4. YIELD TEST DELAY TIME
No action required. Service Message.

5. YIELD TEST OFF
No action required. Service Message.

6. YIELD TEST PURGING.
No action required. Service Message.

7. 2500C TEST OFF
No action required. Service Message.

8. ADJUST CLOCK FREQUENCY OFF
No action required. Service Message.

9. BATT. 14.4V
No action required. Service Message.

10. BATTERY CHARGER TEST OFF
No action required. Service Message.

11. CASE TEMP 25.6C
No action required. Service Message.

12. LEAK TEST 0.0 kPa
No action required. Service Message.

13. FULL BURN TEST
No action required. Service Message.

14. OPTICAL ALIGNMENT TEST
No action required. Service Message.

15. PATIENT VALVE? ELECTRIC
No action required. Set up message

16. PATIENT VALVE? MANUAL
No action required. Set up message

17. YIELD TEST DELAY TIME
No action required. Service Message.

TECHNEGAS LABEL DESCRIPTIONS

1)

ATTENTION, SEE INSTRUCTIONS FOR USE

International Symbol for See Instructions for Use.

2)

CAUTION THIS UNIT MUST BE USED IN ACCORDANCE WITH THE USER MANUAL

This label is located on the front of the Generator Trolley and requests the user to consult their User Manual when using the Generator.

3)

OFF (POWER DISCONNECTION FROM THE MAINS)

International Symbol for power OFF.

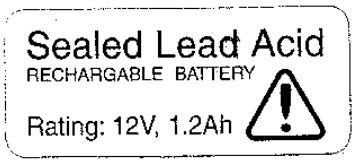
4)

ON (POWER CONNECTION TO THE MAINS)

International Symbol for power ON

5)

SEALED LEAD ACID RECHARGEABLE BATTERY
RATING 12V, 1.2AH



This label is located on the chassis adjacent to the battery and on batteries supplied by Cyclomedica and defines the Generator battery rating.

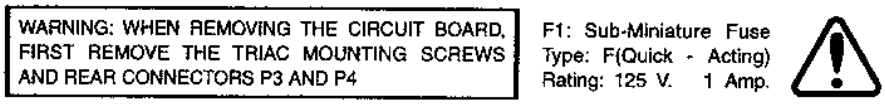
6)

DEPRESS KNOB TO A POSITIVE STOP

This label is located on the Generator cover and requests the operator to push the Patient Knob fully down to release the gas.

7)

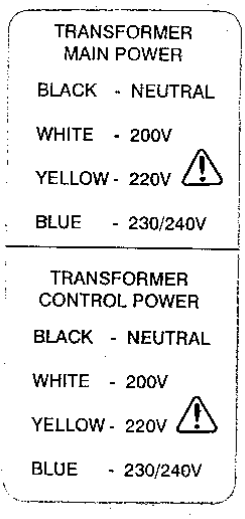
PCB FUSE LABEL


WARNING: WHEN REMOVING THE CIRCUIT BOARD, FIRST REMOVE THE TRIAC MOUNTING SCREWS AND REAR CONNECTORS P3 AND P4
F1: Sub-Miniature Fuse
Type: F(Quick - Acting)
Rating: 125 V. 1 Amp.

This label shows a warning for the removal of the Printed Circuit Board from the unit and also defines the rating of the Printed Circuit Board Fuse in the Battery Charger line.

8)

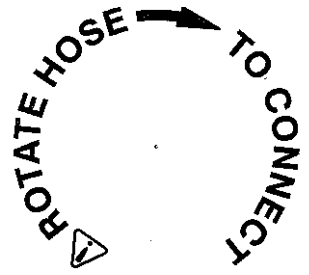
TRANSFORMER TAPPING LABEL



This label defines the voltages for the tapping's of the Generator electrical transformers.

9)

ROTATE HOSE → TO CONNECT



This label is located on the front of the Generator Cover surrounding the Delivery Nozzle. It shows the direction of turn when connecting the Patient Administration Set to the Generator.

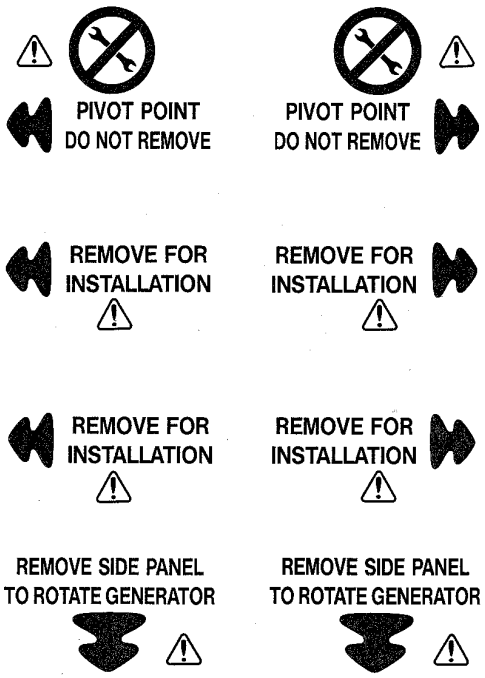
10)

USE ARGON GAS ONLY 'A"

This label is located on the Low Pressure Argon Gas Regulator. It specifies that only ARGON gas be used with the Generator.

11)

INSTALLATION LABELS



These labels are located on the bottom of the Generator Trolley top plate. They define those screws to remove and those to leave in place when rotating the Trolley Top during the installation. Two labels also define the side plate of the Trolley to remove when rotating the Trolley Top.

USER MAINTENANCE

The following are the only user designated tasks for machine maintenance. Extended cleaning should be carried out at the user's discretion. Replacement of the Exhaust Filter and the Contact Assemblies should be carried out when prompted by the Technegas Generator.

A general Service of the Technegas Generator should be carried out by an authorised Service Person after every 150 burns or every six months. This includes a general cleaning and lubrication of the internal components of the Technegas Generator and a calibration check. Please contact your Authorised Representative to request a service for your Technegas Generator.

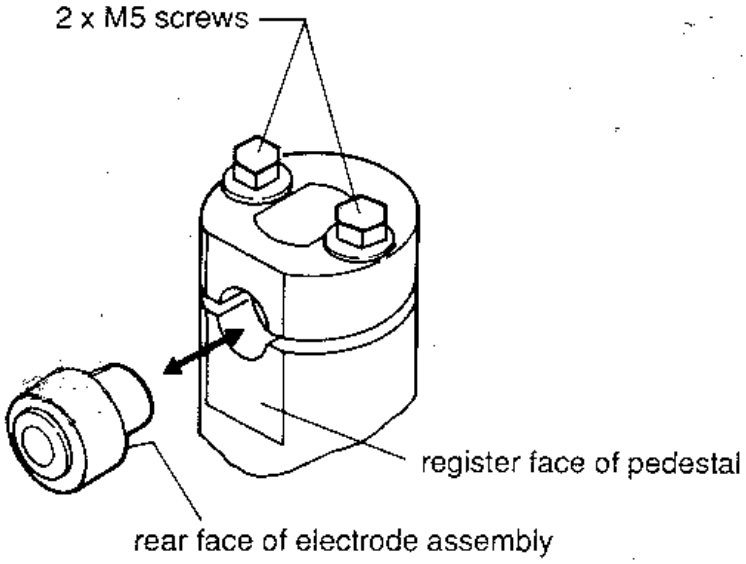
Cleaning the Generator

Clean the outside of the Technegas Generator with a soft cotton cloth. For stubborn stains use a soft cotton cloth slightly moistened with water. There are no user cleanable parts inside the machine. Do Not use Detergents or solvents such as alcohol, benzene or thinners as they will damage the finish of the unit.

Changing Contact Assemblies

Open the drawer, then switch off the power at the mains switch. Loosen the 4 x M5 screws (two in each pedestal) holding the contact assemblies in position. Remove the worn contact assemblies. Fit the new contact assemblies ensuring that the contact areas are clean and that when in position the rear face of both contact assemblies is in contact with the register face of the pedestals. Tighten the 4 x M5 screws to clamp the contacts tightly. **Do not overtighten the screws** as this may result in stripped threads, necessitating major repairs.

Change the contact assemblies every 50 burns
Use disposable gloves as contamination may be present (refer Safety in Use Section)

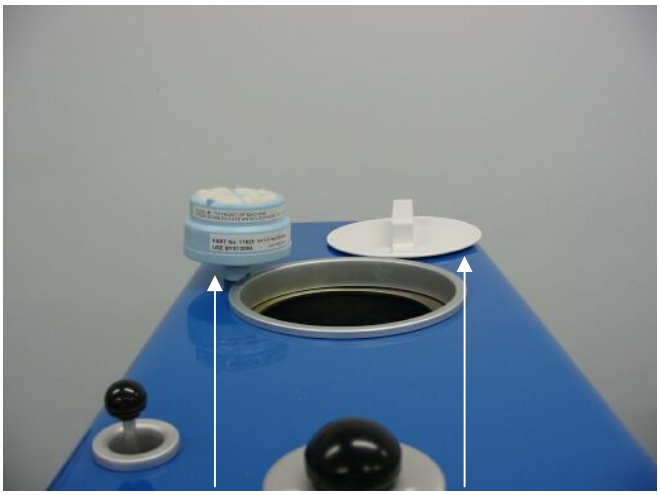


Changing the Purge Filter

It is essential that the purge filter be changed after every 50 burns, ie. when the Technegas Generator prompts you to "Change the Contacts".

Use disposable gloves as the old filter is contaminated. (refer Safety in Use Section).

With the power switched on, the filter is changed by lifting the metal lid on the top of the generator, then removing the old filter by rotating it slightly clockwise (it has a bayonet type fitting). Replace with a new filter and replace lid. Dispose of the old filter as per normal procedure for radioactively contaminated items.



SERVICE

Preventive Maintenance Service

To ensure long term operation and prevention of faults, it is recommended that the Technegas Generator undergo a Preventive Maintenance service each 6 months. Contact your local distributor for service.

General Service of Fault Conditions

Where a fault is perceived in the operation of the Technegas Generator, switch off the machine and call your local distributor for service. Do not operate the Technegas Generator if it is faulty.
For Technegas Generator Service, call your local distributor.

TECHNEGAS GENERATOR SPECIFICATIONS

Protection Against Electric Shock

The Degree of protection against electric shock is as per **CLASS 1 TYPE B EQUIPMENT.**

- denotes **Type B** Applied Part

Electromagnetic Compatibility

The risks associated with the effects of Electromagnetic Emissions and Immunity of the Technegas Generator, have been assessed during a comprehensive Risk Analysis following international standards. The risks associated were determined to be low and the Technegas Generator is unlikely to cause any interference with other equipment.

The Technegas Generator complies with the Immunity and Emissions (Class A compliance) requirements of IEC60601-1-2, Medical Electrical Equipment, General Requirements for Safety, Collateral Standard, Electromagnetic Compatibility - Requirements and Tests.

Electromagnetic Environment Guidance

- *Mains Power Quality for the Technegas Generator should be that of a typical commercial or hospital environment and is not for use on mains power in a domestic environment.*

- *Operators should consider an Electromagnetic Site Survey where their environment is expected to include sources of high level electromagnetic emissions. Where the emissions of your site exceed applicable RF compliance levels, observe the Technegas Generator for correct operation. Under conditions where abnormal operation of the Technegas Generator is observed additional measures may be necessary such as relocating the Technegas Generator.*

Environmental

Ambient Temperature 8-30°C
Ambient Air Pressure 75-108 kPa (750-1080mBar)
Ambient Humidity 0-95% non condensing
Supply Voltage 200 - 230/240 V ~ac ± 5%
Supply Frequency 50-60 Hz

Consumables

Argon Gas

Argon Gas shall be High Purity or Laboratory Grade
≥99.99% pure.

Patient Administration Set

A Patient Administration Set (PAS) designed specifically for the Technegas unit. It is manufactured from a Non-toxic plastic material, with a resin impregnated wool air filter. The PAS is for single use only.

Please note these plastic components can be shredded and recycled.

GENERAL

Duty Cycle -Two procedures per hour.

Mains Current - Steady State < 0.2 Ampere RMS

Mains Current - Maximum (15 sec.) 20 Ampere RMS

Fuse (Battery Charging)F1: Sub-Miniature Fuse
Type: F (Quick Acting)
Rating: 1 Amp 125V..

Shipping Weight 130 Kg
Shipping Size 1060 x 990 x 720mm
Floor Area 920x600

CE 0120

Radiation Dosimetry

Please refer to the package insert of the *Pulmotec*™ crucible for details on Dosimetry

Absorbed dose (adult)/ 37MBq Administered.

Agent	**Lung**	**Wholebody**
Technegas	4.5mGy	0.17mGy
Microspheres (mAA)	2.9mGy	0.16mGy
Reference (R5)		

The Patient

Retention of inhaled Technegas in the lung is dependent on the following parameters:

Depth of breathing
Length of breath holding possible
Basic condition of the patient and lungs
Number of breaths
The initial amount of Technetium added to the *Pulmotec*™ crucible
The time after generation that the patient breathes in the Technegas

It is important to monitor the activity of the Technegas in the patient as the Technegas is administered by watching the count rate of a posterior view on the gamma camera console. Limit the dose to that indicated in the clinical notes (40MBq). This is generally a maximum of approximately 2500 counts per second (cps).

Note: If thyroid is present in images or absorption of Technegas into the blood stream is noted operators should check that they have used Argon gas of 99.99% purity. Operators should also ensure that they have used the correct eluate and have not over-filled the crucible. If such indications are present after checking these points then the operator should call their local service provider.

TECHNEGAS GENERATOR SPARES

CODE	DESCRIPTION
17838	Box of 50 Patient Administration Sets (REST OF THE WORLD)
17839	Box of 50 Patient Administration Sets (EUROPE)
10035	Patient Nose Clamp (1 only)
10036	Pair of Forceps
10029	Ash Tray
10039	User Manual
17544	Maintenance Pack
17605	*Pulmotec*™ Crucibles (Pack of 10)
10040	Argon Gas Regulator Assembly Complete (Includes Supply Hose)

Refer to the Service Manual for details of Service parts.

References

W M Burch, P J Sullivan and C J McLaren: Nuclear Medicine Communications, 7, 865-872 (1986).

H W Kroto, J R Heath, S C O'Brien, R F Curl, and R E Smally: Nature Vol 318 Nov. 1985 pp 162-163.

Friedlander S K. Smoke dust and haze. New York: Wiley, 1977; 297.

Clinical Nuclear Medicine. Edited Maisley et al, Chapman & Hall (1983) pp73.

Kereiakes J G, Rosenstein M: Handbook of Radiation doses in Nuclear medicine and diagnostic X-ray. Florida: CRC Press, 1980.

A full discussion of the technology and bibliography may be found at http://www.Cyclomedicamedical.com.au